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Bouboulis

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(54) **APPARATUS AND METHOD FOR TREATING RHINITIS**

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(52) **U.S. Cl.**
CPC **A61N 5/0603** (2013.01); **A61N 2005/0607** (2013.01); **A61N 2005/0644** (2013.01); **A61N 2005/0659** (2013.01)

(58) **Field of Classification Search**
USPC 607/88, 89
See application file for complete search history.

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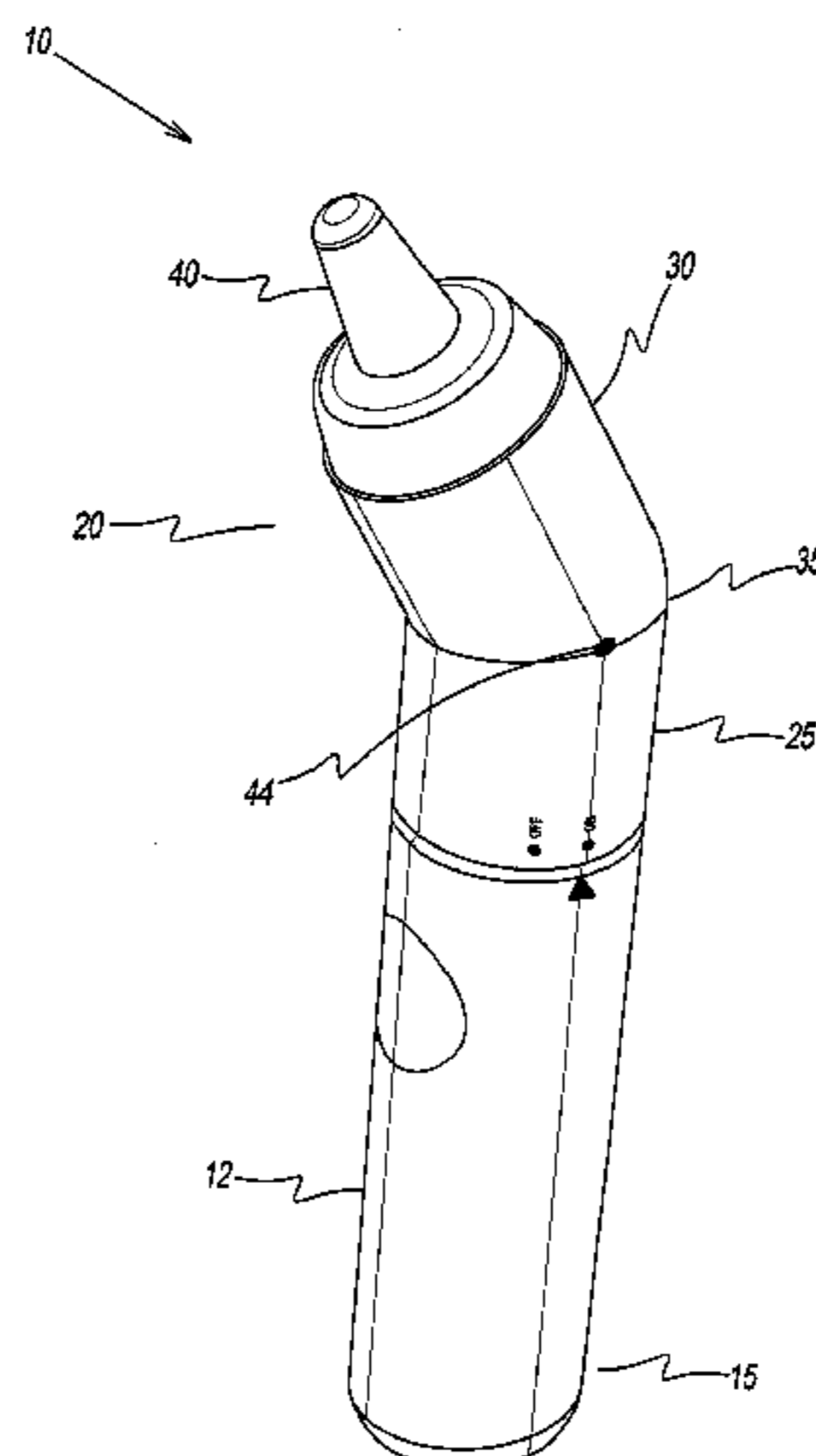
Primary Examiner — Jeffrey Lipitz

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(57) **ABSTRACT**

A device for delivering light to a nasal cavity includes a base; an adjustable portion operably connected to the base. The adjustable portion permits ready manipulation of the device when in the nasal cavity. The adjustable portion includes a tapered tip for insertion into the nasal cavity; a light source disposed inside of the tapered tip; and a power source to supply power to the device.

20 Claims, 16 Drawing Sheets



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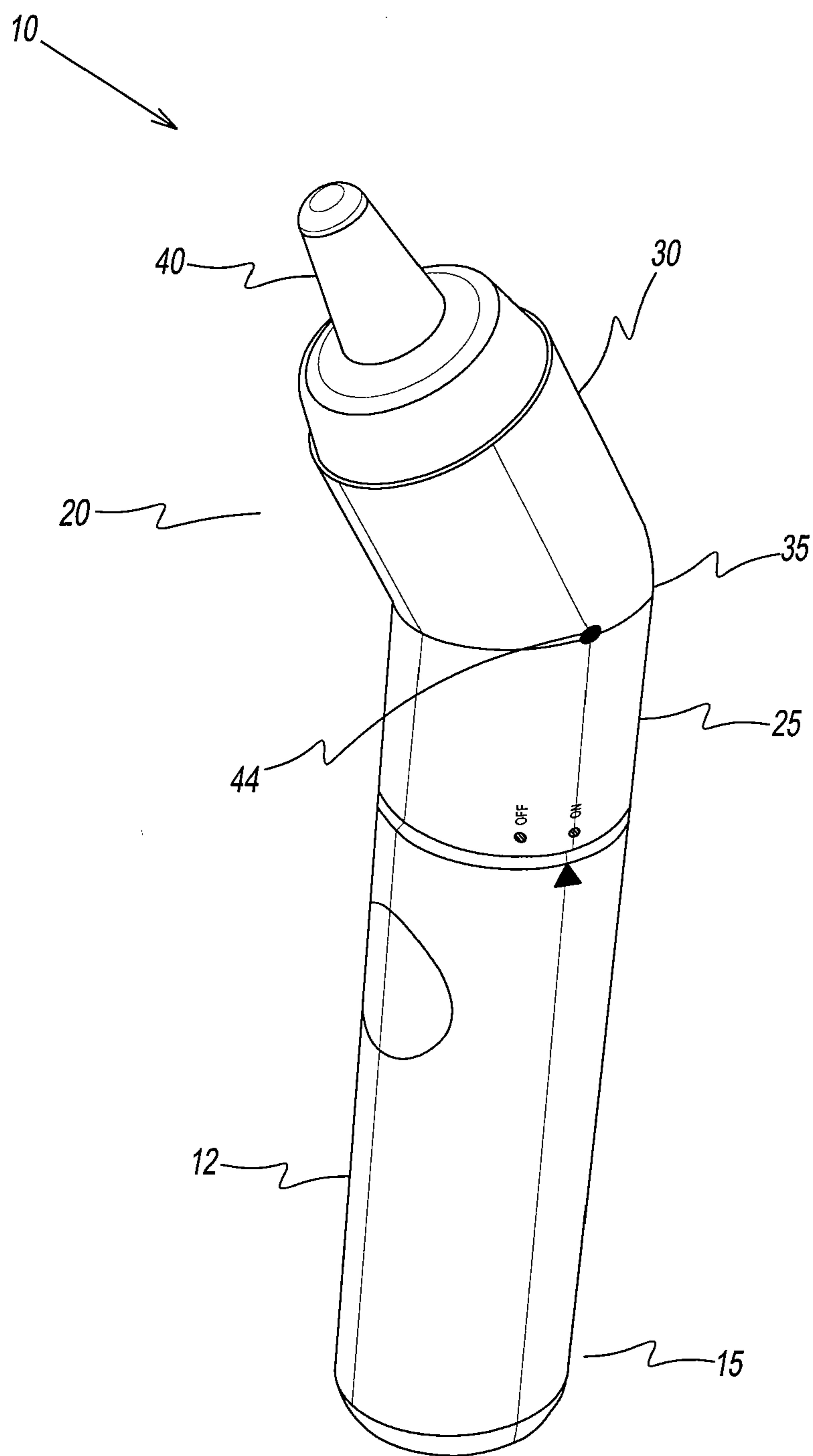


FIG. 1

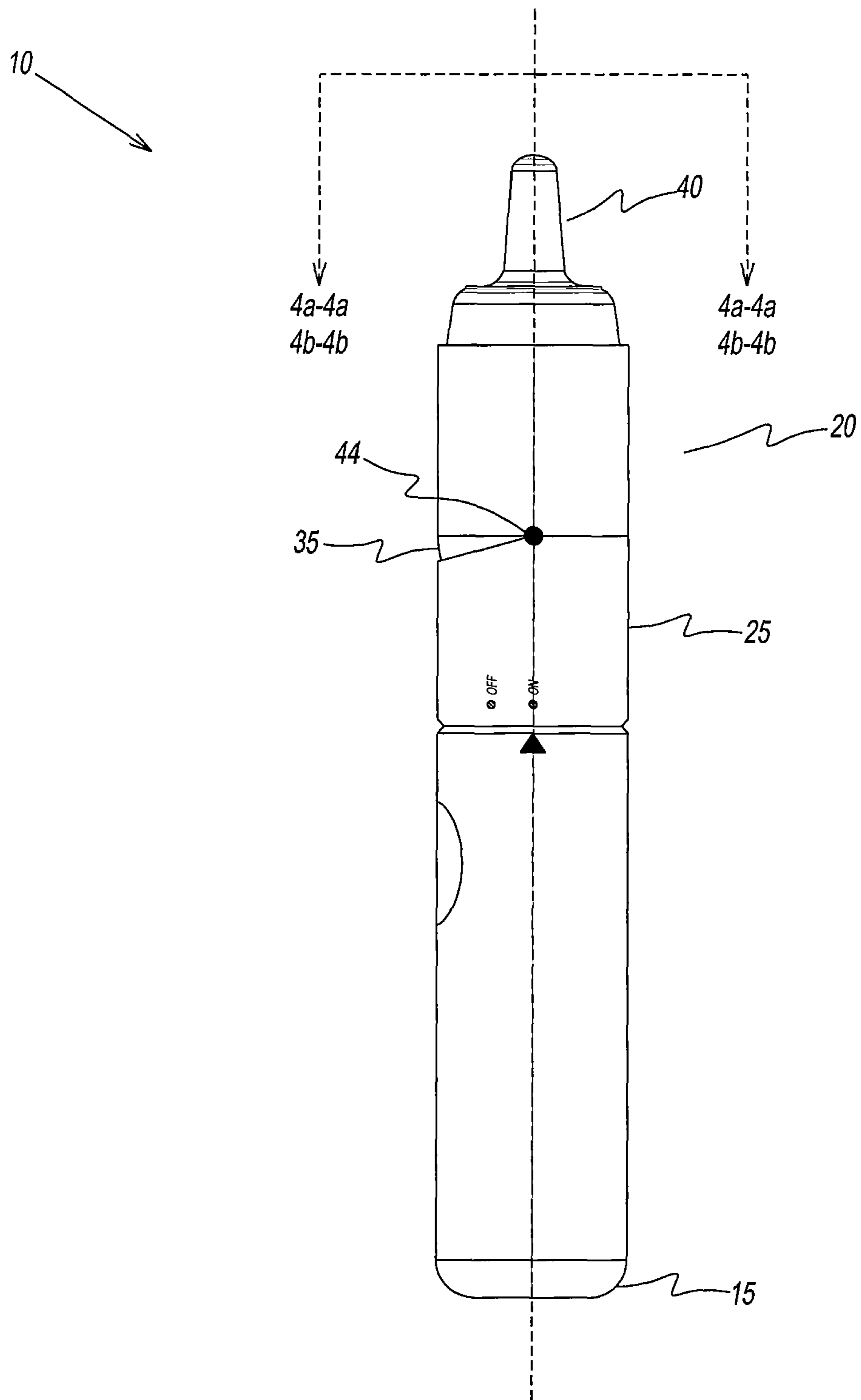


FIG. 2

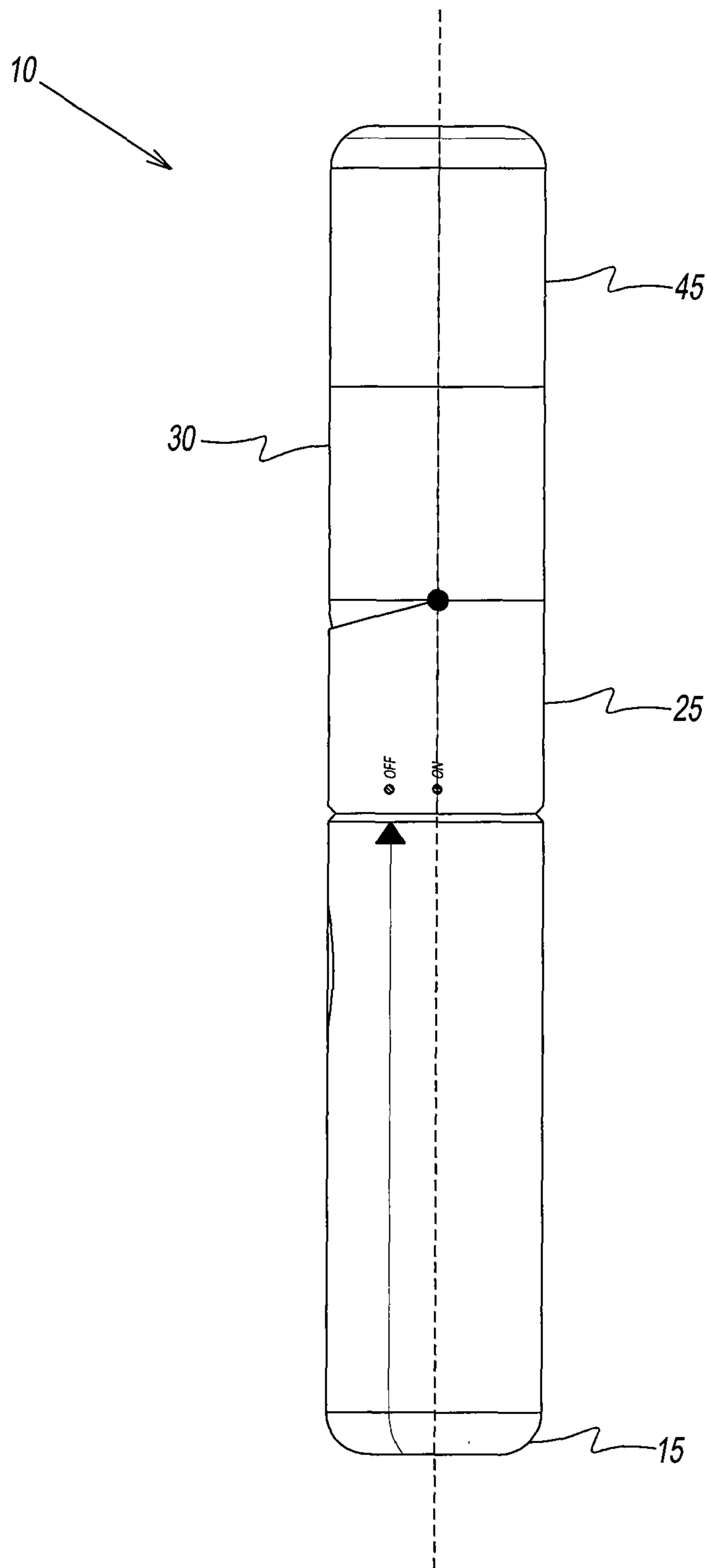


FIG. 3

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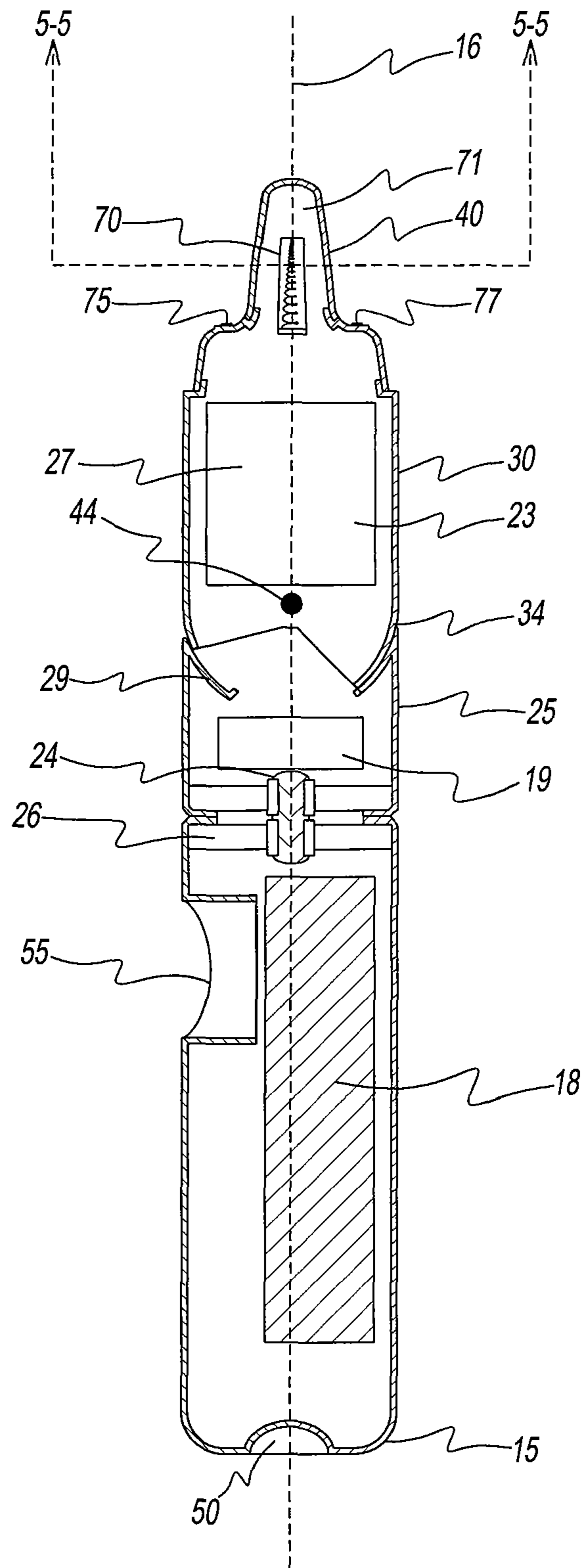


FIG. 4A

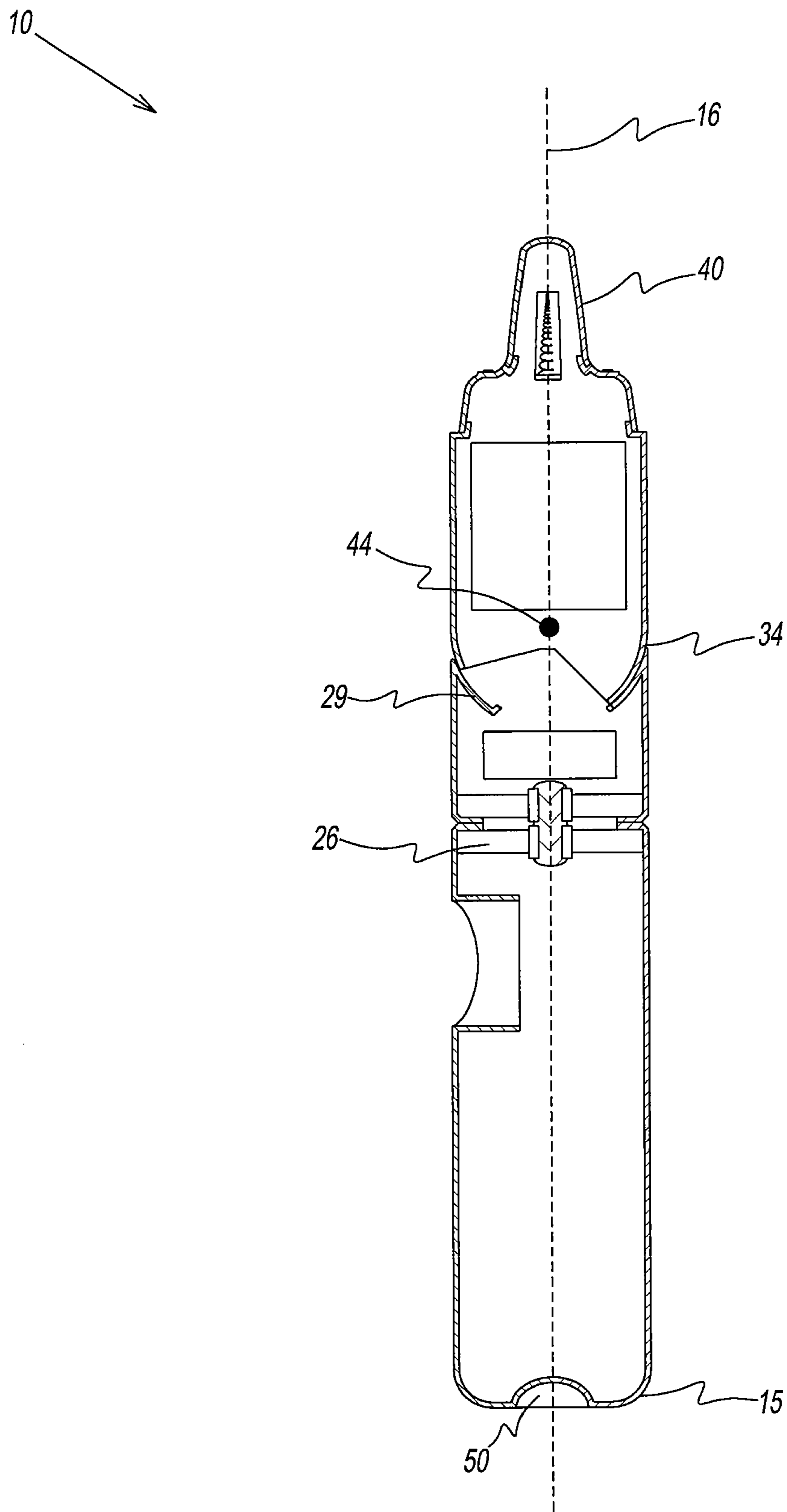


FIG. 4B

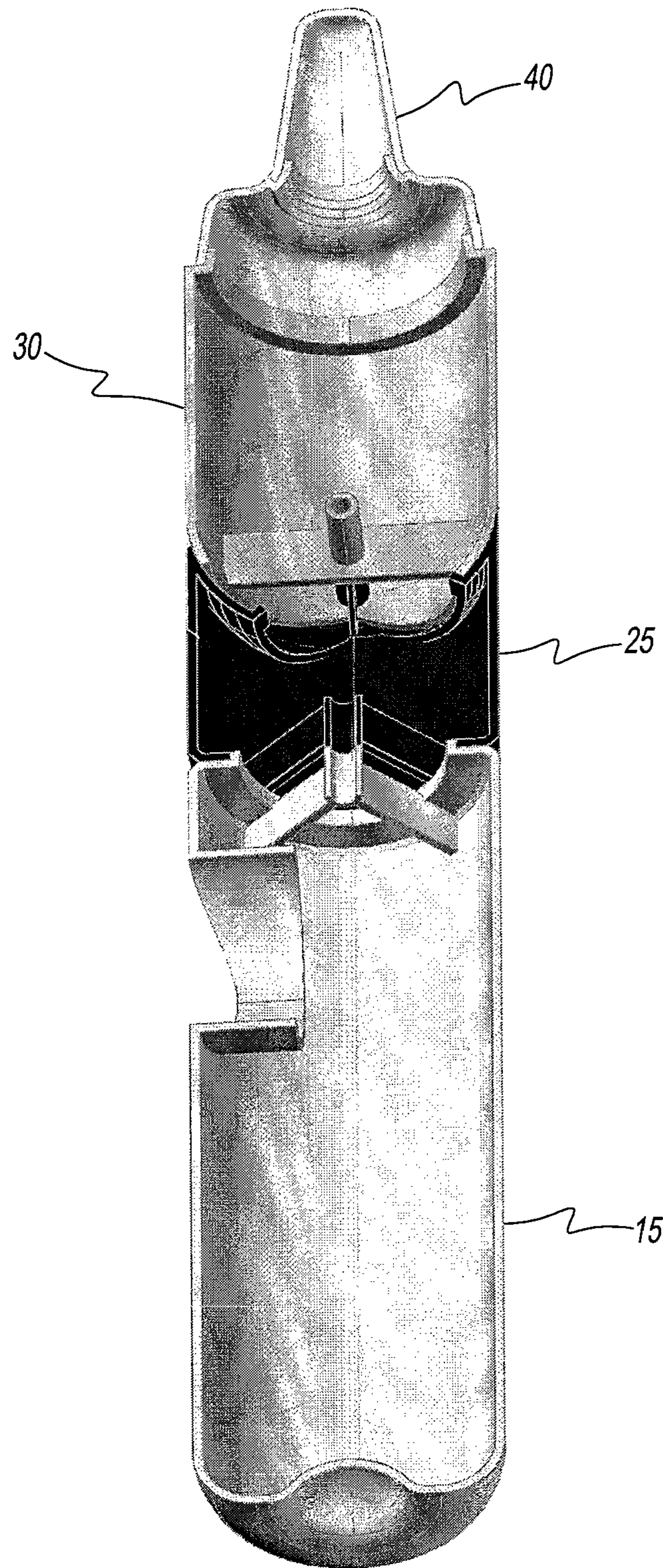


FIG. 4C

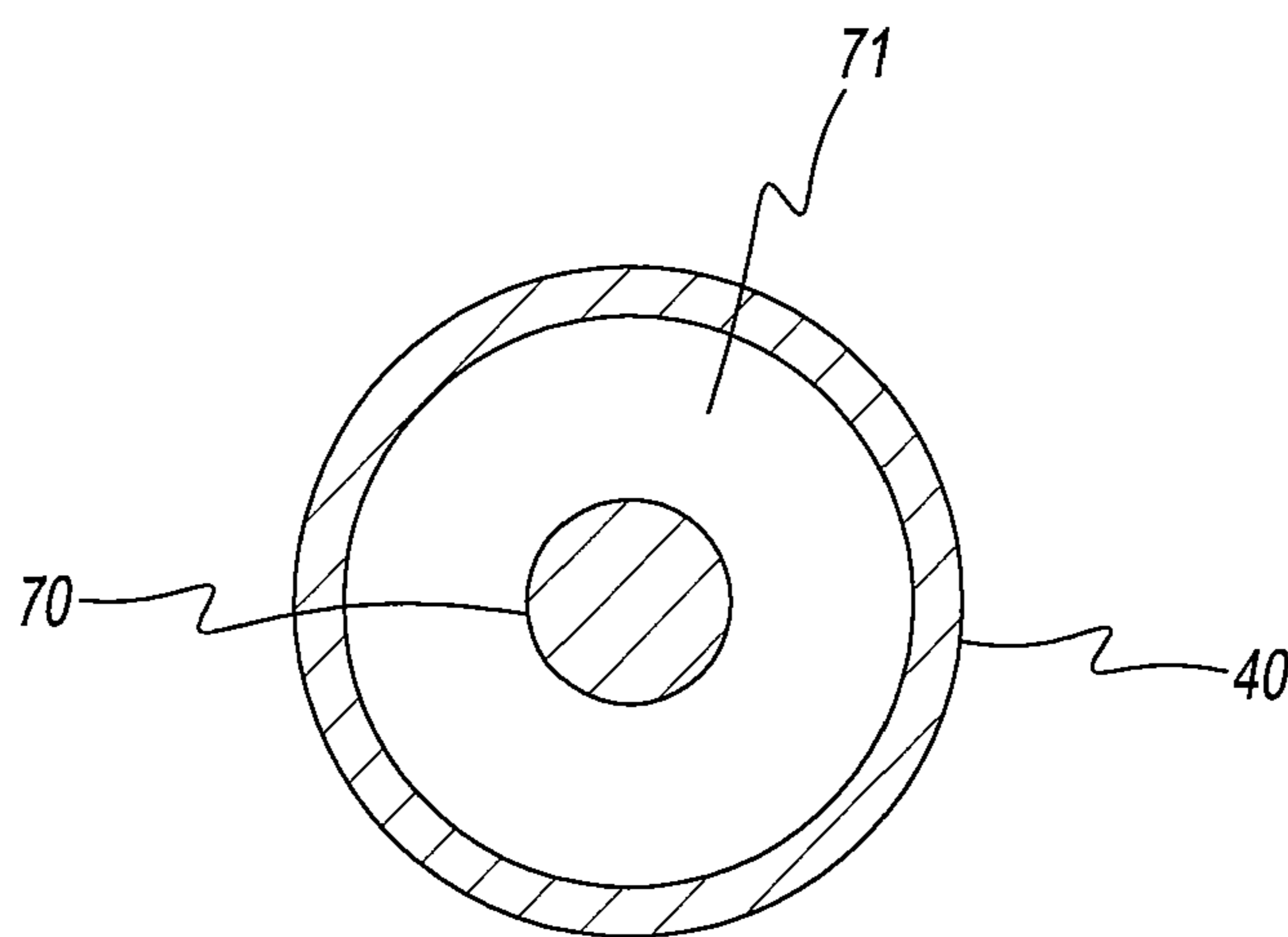


FIG. 5

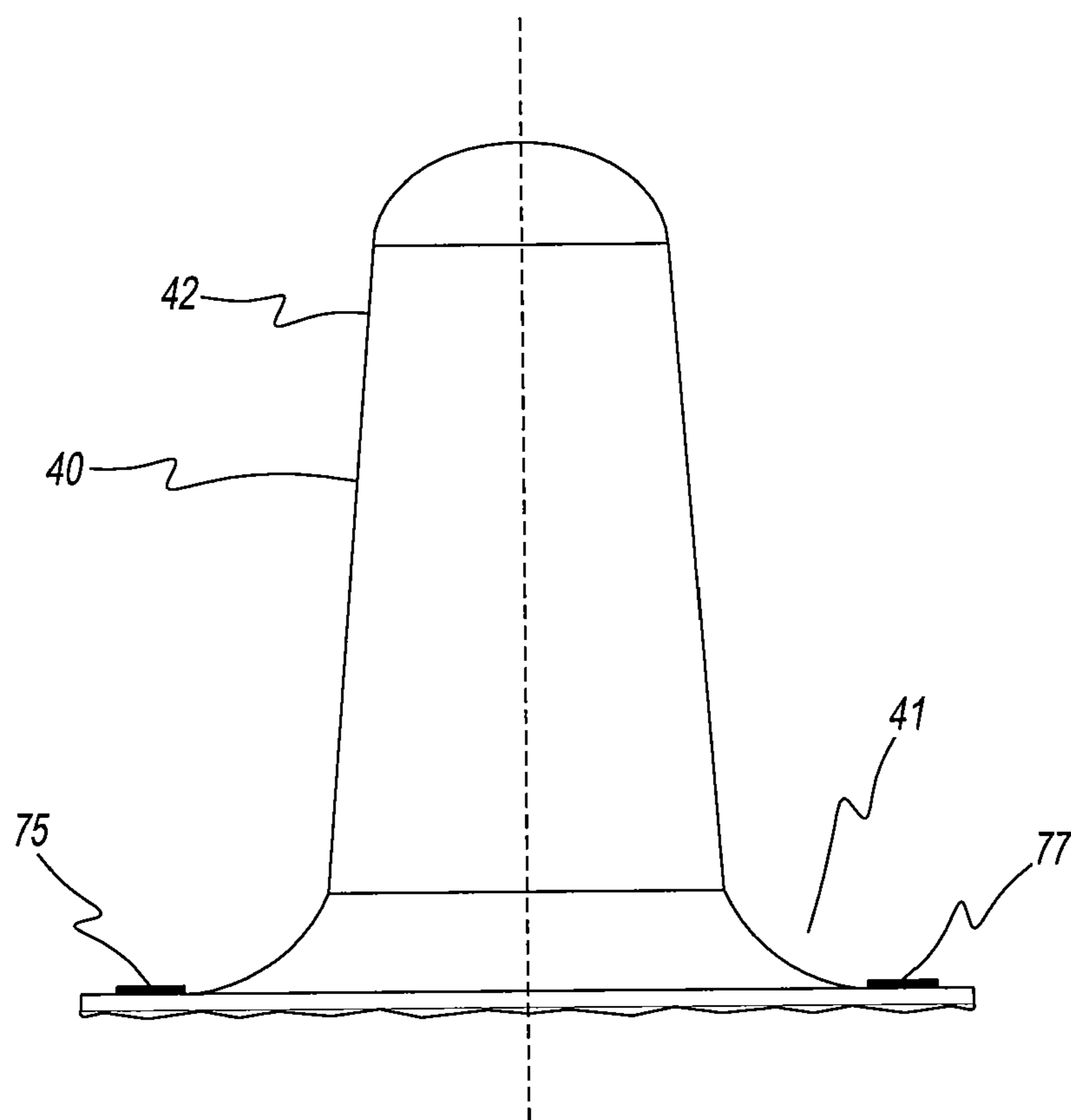


FIG. 6

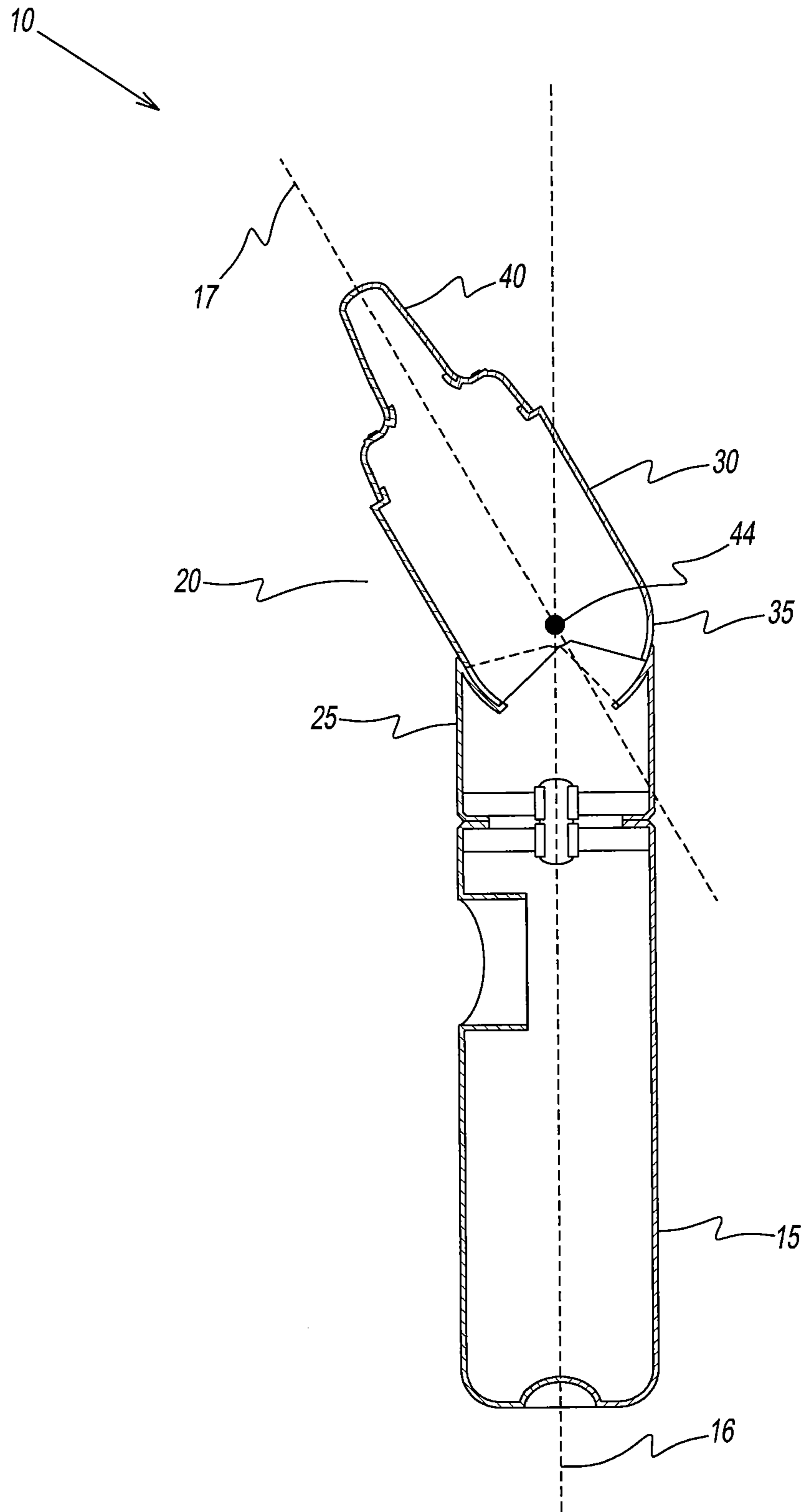


FIG. 7A

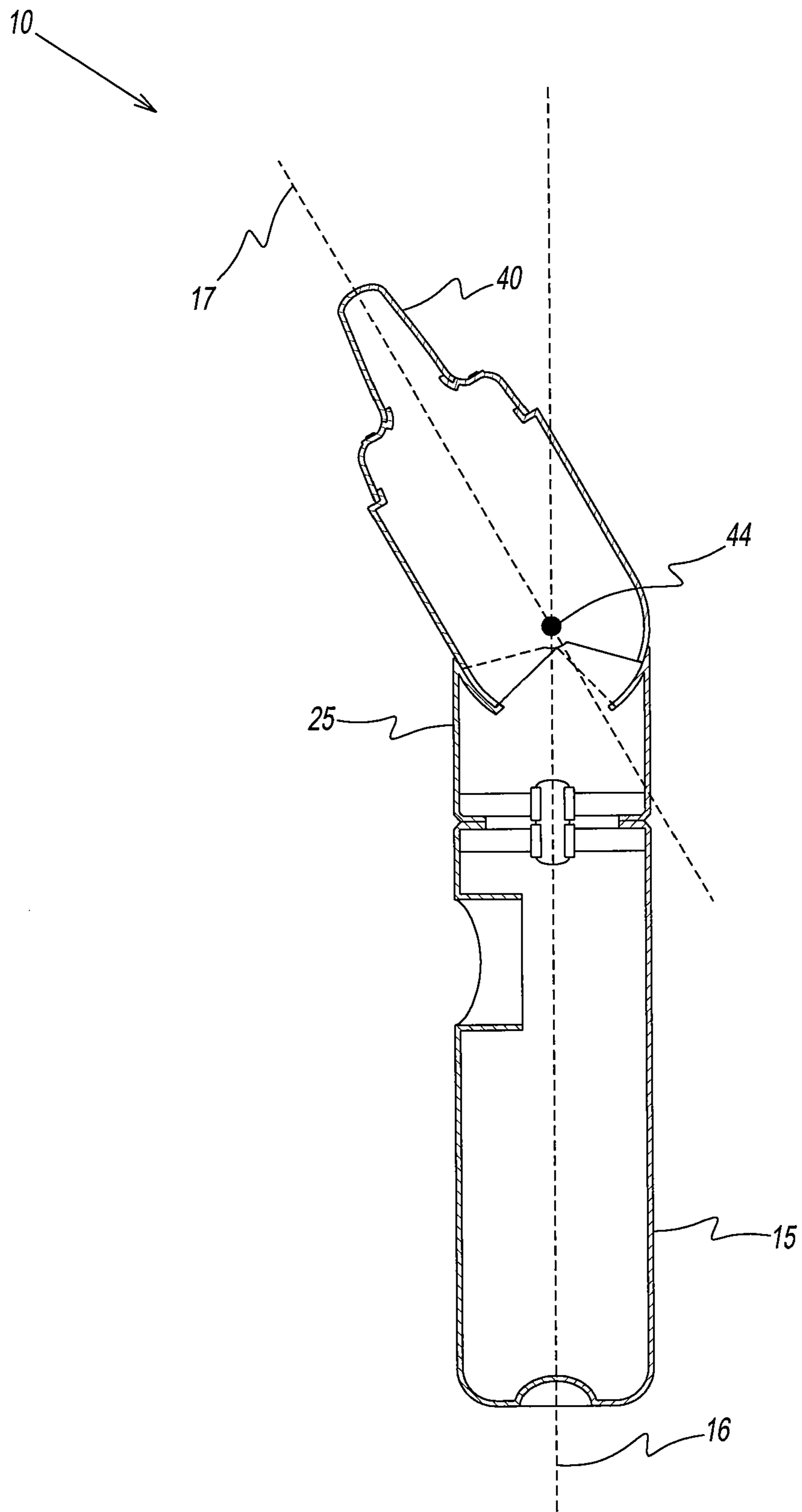


FIG. 7B

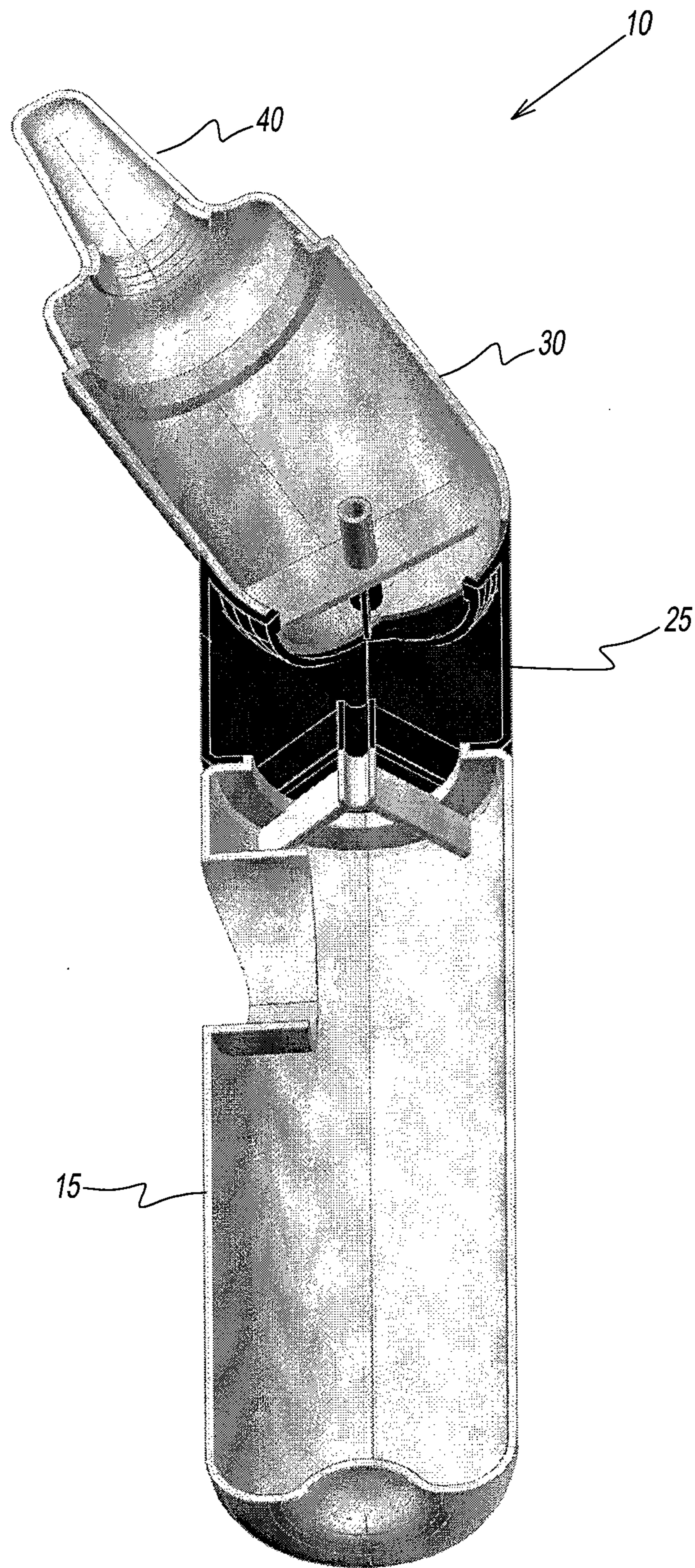


FIG. 7C

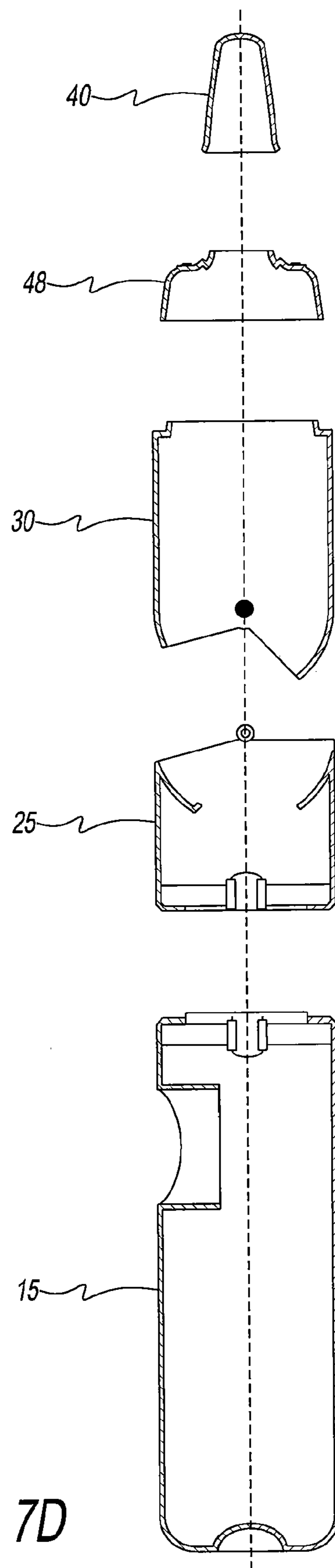


FIG. 7D



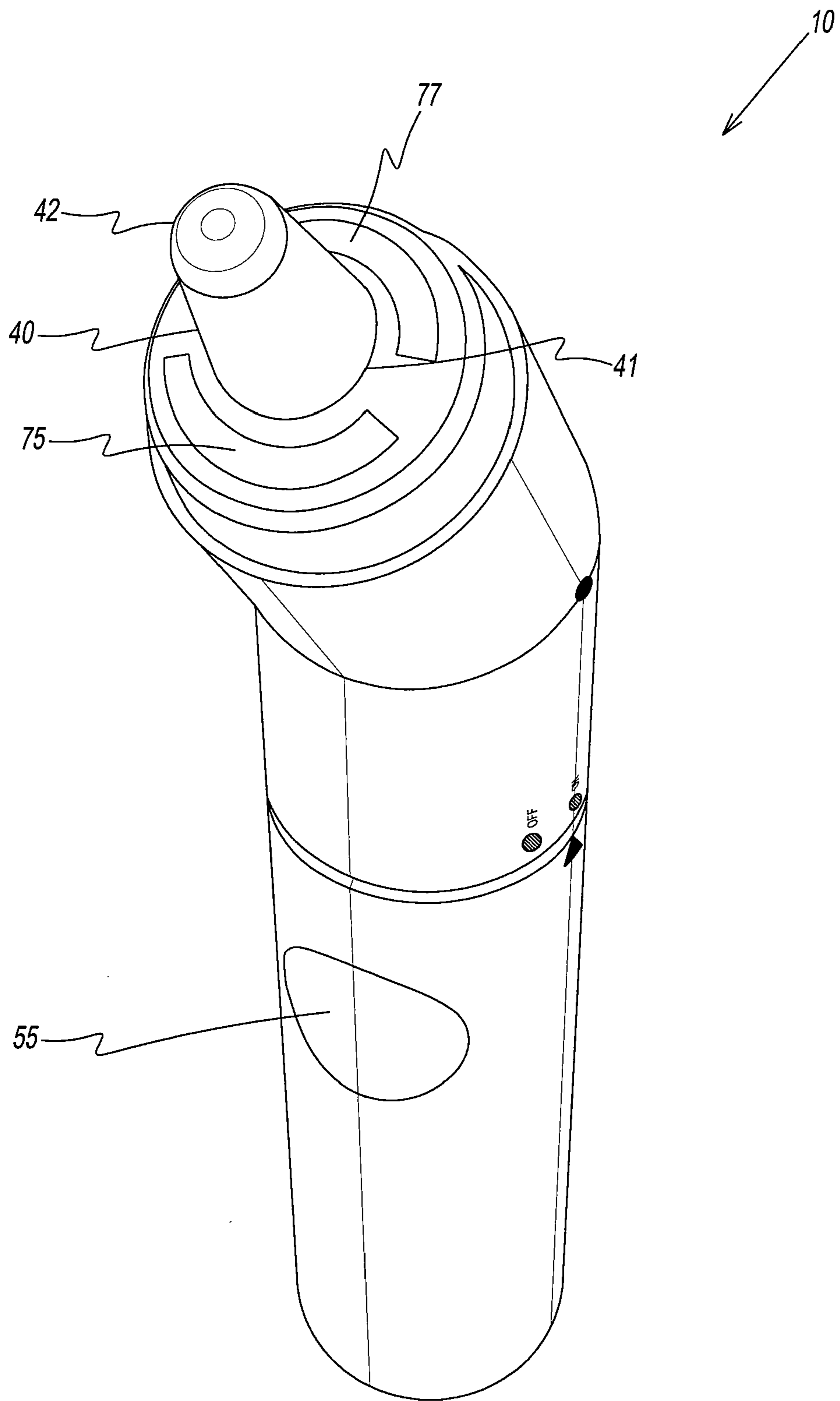


FIG. 8

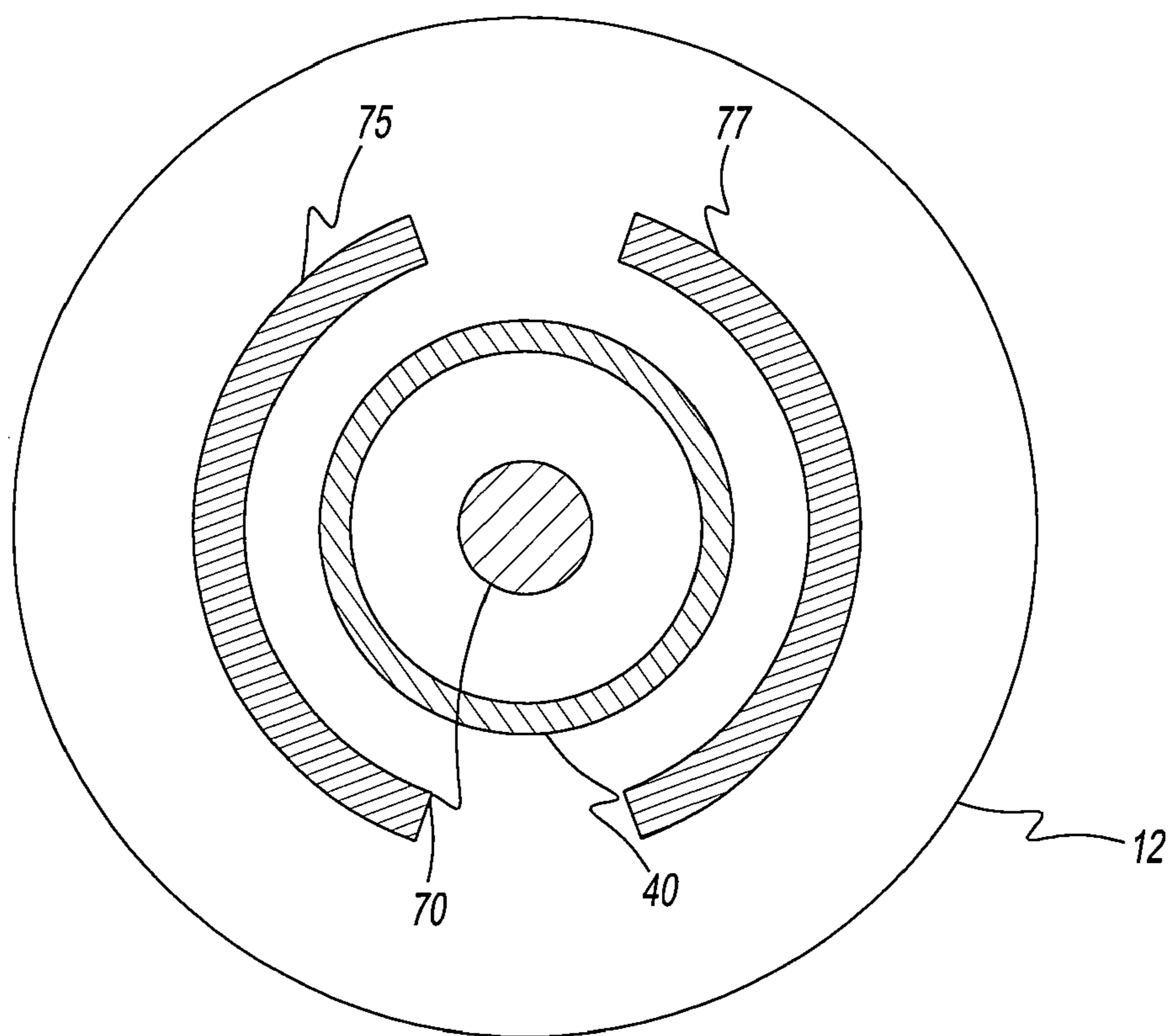


FIG. 9

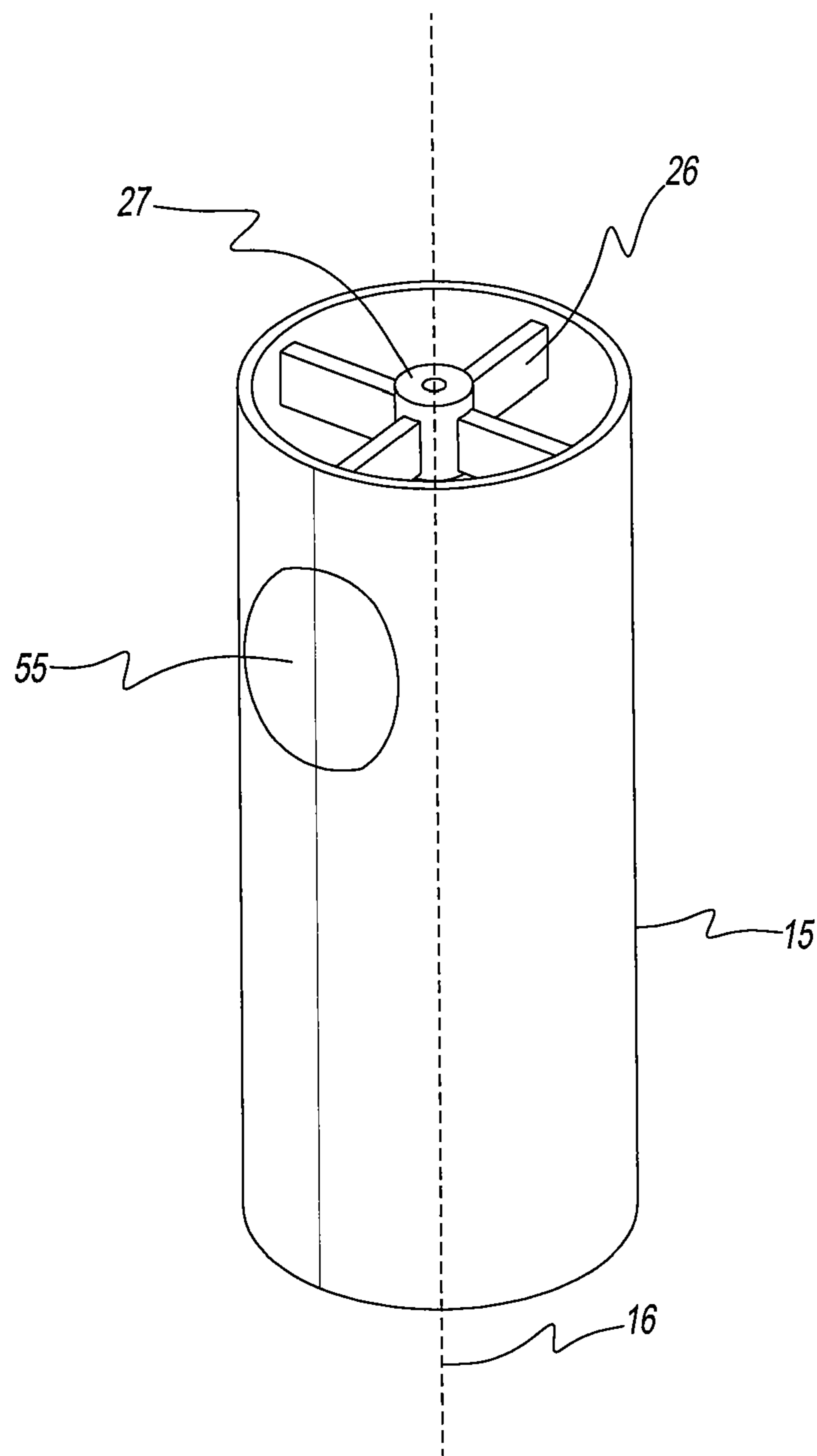


FIG. 10

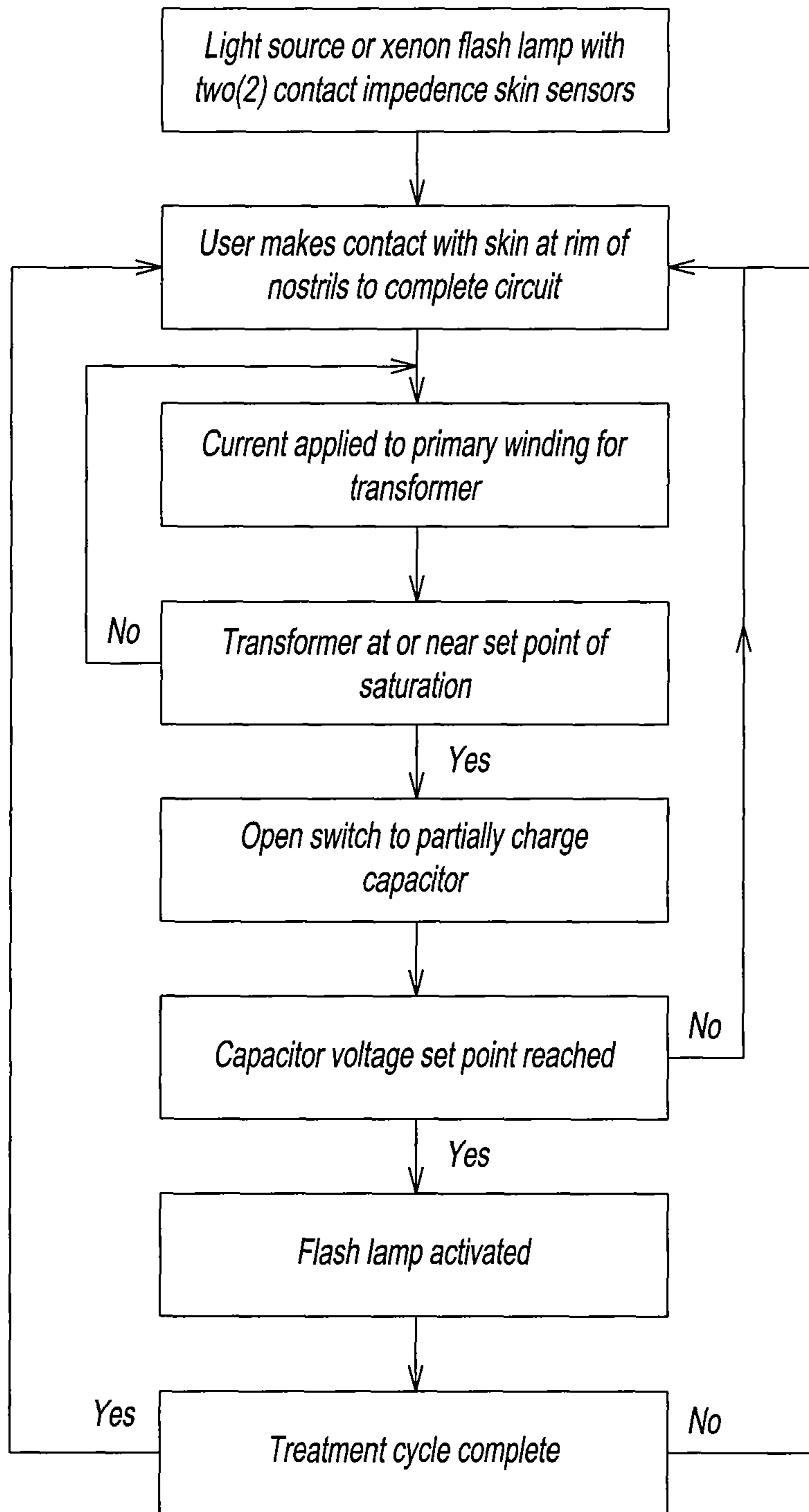


FIG. 11

APPARATUS AND METHOD FOR TREATING RHINITIS

BACKGROUND OF THE DISCLOSURE

1. Field of the Disclosure

This disclosure relates to the use of phototherapy to treat the symptoms of seasonal and perennial allergic rhinitis.

2. Description of Related Art

Allergic rhinitis (also commonly known as hay fever) is a condition that occurs when allergens such as pollens cause inflammation of mucous membranes in the nose. Symptoms including sneezing, itching, nasal discharge, and/or congestion. Perennial and seasonal allergic rhinitis afflict millions of persons throughout the world.

Treatment of allergic rhinitis has traditionally been accomplished through the use of systemic medications, antihistamines, decongestants, steroids, and long-term immunotherapy. Each of these treatment modalities has advantages and disadvantages but typically no single modality or combination of modalities can completely relieve all of the symptoms of allergic rhinitis.

In contrast to and/or as a supplement to those traditional treatments, phototherapy has relatively recently been found to be effective in treating allergic rhinitis. Although phototherapy has been used for many years to treat various skin conditions (such as acne, psoriasis, pigmented lesions, and wounds, and to help tighten sagging skin, reduce wrinkles, and stimulate circulation, to name a few), and lasers have been used in surgical applications (including to treat various conditions in the nasal cavity such as lesions, polyps etc.), studies have recently shown that phototherapy can also be used to help temporarily reduce or eliminate symptoms of allergic rhinitis. The present disclosure provides a convenient, safe, and affordable device and methodology for making available that treatment.

SUMMARY OF THE DISCLOSURE

The present disclosure provides for the utilization of phototherapy in the treatment of allergic rhinitis.

The present disclosure also provides a device that stimulates the human body's own respiratory system to reduce symptoms of allergic rhinitis.

The present disclosure further provides for a convenient and inexpensive device that enable allergy sufferers to be effectively treated.

The present disclosure also provides for a device that has a tapered tip for insertion into a nasal cavity and a light source within such tapered tip that is able to illuminate such nasal cavity for phototherapeutic treatment of rhinitis.

The present disclosure further provides for such a device that has a tapered tip for insertion into a nasal cavity and a light source that provides for circumferential light delivery within such tapered tip to maximize exposure of the nasal tissue to the light source.

The present disclosure also provides for a handheld apparatus for nasal application of phototherapy that has a straight portion and an adjustable portion. The adjustable portion has two parts that are movable relative to each other to form a hinge/joint that permits the user to adjust the angle of insertion of the tapered tip of the adjustable portion into the nasal cavity.

The present disclosure further provides for a safety feature that prevents activation of a light source for phototherapy

treatment until after a circuit has been completed that indicates that nasal tip has been inserted into a nasal cavity of a user.

The present disclosure still further provides for a safety feature that is a contact switch having two curved portions that correspond to the curvature of the outer portion of a nostril. When such curved portions are depressed during insertion, a circuit is completed to permit activation of a light source in a nasal insertion tip for the treatment of rhinitis.

The present disclosure yet further provides for a methodology of treating rhinitis using phototherapy by illuminating a nasal cavity with light in the wavelength of from 600-950 nm. The light can be generated by a gas flashlamp, an IR light source, a laser diode, an LED, fiber optic cable or bundle other suitable means. The light is delivering in a quantity of from 12 to 24 joules/cm² of light energy. When the light is a flashlamp, a wavelength of from 600 nm to about 690 nm can be used although a range of from 650 nm to 660 nm is preferred. When infra-red light is used a range of from 700 nm to 950 nm can be used although a range of from about 700 to 900 is preferred.

A device for delivering light to a nasal cavity includes a base; an adjustable portion operably connected to the base. The adjustable portion, permits ready manipulation of the device when in the nasal cavity. The adjustable portion includes a tapered tip for insertion into the nasal cavity; a light source disposed inside of the tapered tip; and a power source to supply power to the device.

A device for delivering light to a nasal cavity includes a housing having a tapered tip and two or more portions; and a joint that permits an angle to be formed between the two portions of the housing. The device also includes a light source disposed within the tapered tip for illumination of the nasal cavity; and a safety feature that restricts delivery of light from the light source to the nasal cavity. A power source to supply power to said housing.

A device for delivering light to a nasal cavity includes a housing having a tapered tip; and a light source inserted within the tapered tip to illuminate the nasal cavity. The device also includes a safety feature disposed on the housing that detects contact or pressure between the safety feature and a nostril of a user to enable illumination of the light source. The device provides a power source to supply power to the housing.

A method for treating rhinitis includes generating light in a wavelength of approximately 600 nm-950 nm; providing light to a user's nasal cavity by insertion of a light source, by inserting at least a portion of the light source into the nasal cavity; and delivering a dosage of approximately 12 to 24 Joules/cm² of light energy to the user's nasal cavity. When the light source is a flashlamp, a wavelength of from 600 nm to about 690 nm can be used although a range of from 650 nm to 660 nm is preferred.

When the light source is an infra-red light is used a range of from 700 nm to 950 nm can be used although a range of from 700 to 900 is preferred.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the device of the present disclosure in an angled configuration;

FIG. 2 is a side view of the device of FIG. 1 in a straight configuration;

FIG. 3 is a side view of the device of FIG. 1 in a with a safety cap covering the nasal insertion tip;

FIG. 4a is a cross-section view of the device taken along line 4a-4a of FIG. 1;

FIG. 4b is a partial cross-section of a rendition taken along line 4b-4b of the device of FIG. 1,

FIG. 4c is a partial cross-section of a rendition of the device of FIG. 1, showing the axial rotation mechanism.

FIG. 5 is a cross-section view of the device of FIG. 1, taken along line 5-5;

FIG. 6 illustrates a schematic view of the nasal tip of the device of FIG. 1;

FIG. 7a is the device of FIG. 4, with the device in an angled configuration;

FIG. 7b is a partial rendition of the device of FIG. 7a;

FIG. 7c is a partial rendition of the device of FIG. 7a;

FIG. 7d is an exploded view of the device of FIG. 7a;

FIG. 8 is a front perspective view of the device of FIG. 1;

FIG. 9 is a top view of the device of FIG. 2;

FIG. 10 is a perspective view of the base of the device of FIG. 1; and

FIG. 11 is a flowchart illustrates methodology of using the device of FIG. 1.

DETAILED DESCRIPTION OF THE DISCLOSURE

Referring to the drawings and, in particular, to FIG. 1, a phototherapy device is shown and generally referenced by reference numeral 10. Device 10 has a housing 12 with a base 15 and an adjustable portion 20. Adjustable portion 20 includes a sleeve 25 and an endpiece 30. Endpiece 30 has a curved end 35 and an insertion tip 40. Insertion tip 40 contains a light source 70 as shown in FIG. 4 that may be activated to treat allergic rhinitis. Curved end 35 is secured to sleeve 25 to permit endpiece 30 to pivot relative to sleeve 25 about pivot points 44 (one shown). FIGS. 1 and 7 illustrate device 10 in an adjusted configuration with endpiece 30 pivoted about points 44 relative to sleeve 25.

FIGS. 2 and 4a through 4c illustrate device 10 in a straight configuration in which endpiece 30 is co-axial or in a non-bent configuration relative to sleeve 25. In the straight configuration, curved end 35 is partially shown and partially hidden inside of sleeve 25. Device 10 is preferably a handheld device for purposes of enhanced portability having an overall length of approximately 6 inches in a straight configuration.

FIG. 3 shows device 10 having a safety cap 45 positioned over insertion tip 40 and secured to endpiece 30 to protect insertion tip 40 from damage. At opposite end of device 10 from safety cap 45, base 15 has a charging coupling 50, as shown in FIG. 4a. Charging coupling 50 permits device 10 to be charged periodically via a power source such as a rechargeable battery 18 by insertion into an induction charging unit (not shown) to maintain power in device 10 for adequate operation when needed.

Referring to FIG. 4a, device 10 has insertion tip 40, is shown. Insertion tip 40 is made from a medical grade transparent plastic that can withstand repeated exposure from light source 70. Transparent plastic permits a maximum amount of light emitted from light source 70 to be delivered to tissue of nasal cavity. Were insertion tip 40 made from a material that is opaque, the amount of light that would be delivered to tissue of nasal cavity for treatment would be lessened and optimal efficacy would not be achieved. Further, the material of insertion tip 40 acts as a filter to only permit light between predetermined wavelengths to be transmitted. When the light source 70 is a flashlamp, a wavelength of from 600 nm to about 690 nm can be used although a range of from 650 nm to 660 nm is preferred. Accordingly, insertion tip 40 will be constructed of a plastic that permits light in a wavelength of from 600 nm to 690 nm or 600 nm to 660 nm to pass there-

through. When light source 70 is an infra-red light is used a range of from about 700 nm to 950 nm can be used although a range of from 700 nm to 900 nm is preferred. Accordingly, insertion tip 40 will be constructed of a plastic that permits light in a wavelength of from about 700 nm to 950 nm, and preferably from 700 nm to 900 nm to pass therethrough. Insertion tip 40 may be connected to a surround 48 or insertion tip 40 and surround 80 may be unitary in construction.

Referring to FIG. 5, insertion tip 40 has an air cavity 71 between light source 70 and inner surface of insertion tip 40. Air cavity 71 functions as an insulator and prevents damage to sensitive tissue of nasal cavity. Air cavity exists around light source and has a thickness of from 2 mm to 5 mm. Air cavity may 71 may contain a gas, such as xenon, for purposes of illumination.

Referring to FIG. 6, insertion tip 40 is tapered from a tip base 41 to tip end 42. Insertion tip 40 ranges in length from approximately 0.6 to 1.0 inches (15.24 mm to 25.40 mm). Tip base 41 has a diameter of approximately 0.3 to 0.5 inches (7.62 mm to 12.70 mm), and tip end 42 has a diameter of from 0.22 to 0.3 inches (5.58 mm to 7.62 mm). These ranges of dimensions ensure that insertion tip 40 will have optimal contact with engorged or enflamed tissue in an individual suffering from seasonal allergies. Further, tip end 42 has a radius of 0.06 in to 0.12 inches (1.52 mm to 3.05 mm) to ensure comfort during use.

Referring to FIG. 4a, device 10 has a longitudinal axis 16 that extends from base 15 through sleeve 25 to insertion tip 40. FIG. 7 shows adjustable portion 20 and, in particular, endpiece 30 at an angle relative to sleeve 25. In the angled configuration, endpiece 30 has a longitudinal axis 17 that has an angle of 30 degrees relative to longitudinal axis 16 of base 15 and sleeve 25. Endpiece 30 can be positioned by user at any angle from 0° to 40° to achieve the most comfortable angle for positioning inside of the nasal cavity. Angles between 10° to 30° represent a mid-range of use for users and angles from 25° to 30° are optimal for comfort and efficacy. Sleeve 25 is a substantially hollow member that is pivotally fixed to endpiece 30 at pivot points 44. Endpiece 30 has a curved end 35 that moves in sleeve 25 during pivoting movement about pivot points 44 to change angle between sleeve 25 and endpiece 30. Endpiece 30 is maintained at angle in sleeve 25 by friction between endpiece surface 34 and sleeve surface 29.

Contained within endpiece 30 is light source 70, as shown in FIG. 4a. Light source 70 is shown as being a flashlamp, such as a xenon flashlamp, although other light sources 70, such as an infra-red light, an LED, fiber optic cable, or a laser could be used. For any embodiment of the light source, the power density of the delivered light is 12 to 24 joules/cm². When light is delivered at this power density through insertion tip 40 into the nasal cavity of a user, treatment of rhinitis and seasonal nasal allergies is achieved. Light source 70 has a longitudinal axis that coincides with longitudinally axis 17 of insertion tip 40. The coincident axes ensure optimal placement of light source relative to insertion tip 40 provide circumferential delivery of light to nasal tissue to light source 70. If light source was placed in an alternative fashion, circumferential delivery of light would not be achieved and optimal phototherapy treatment would be compromised.

Referring to FIGS. 4a, 8 and 9, insertion tip contains safety contacts 75, 77 proximate to tip base 41. Safety contacts 75, 77 are arcuate and almost semi-circular in configuration. Safety contacts 75, 77 contact outer surface of nostril to enable light to illuminate. Contacts 75, 77 are impedance sensors and actual contact between skin around nostril opening completes a circuit to permit light source to be activated by depressing trigger 55. With impedance sensors 75, 77, if the

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skin on both sides of nostril is not in contact with sensors, light source will not illuminate insertion tip 40. Impedance sensors 75, 77 have an arcuate and almost semi-circular shape to correspond to the outer surface of nostril.

Alternatively, when safety contacts 75, 77 are depressed during insertion into nasal cavity, a circuit is completed that permits light source to be activated by depressing trigger 55. If safety contacts 75, 77 are both not depressed, light will not be illuminated. Safety contacts 75, 77 ensure that light source will not be accidentally activated with depression of trigger 55, until insertion tip 40 is inserted and in contact with outer surface of nostril. Accidental exposure to light from light source 70 could damage the eyes of user or those of a nearby individual. Significantly, each safety contacts 75, 77 has an arcuate and almost semicircular shape to correspond to the outer surface of nostril.

Alternatively, contacts 75, 77 are impedance sensors and actual contact between skin around nostril opening completes a circuit to permit light source to be activated by depressing trigger 55. With impedance sensors 75, 77, if the skin on both sides of nostril is not in contact with sensors, light source will not illuminate insertion tip 40. Impedance sensors 75, 77 have an arcuate and almost semi-circular shape to correspond to the outer surface of nostril.

Referring again to FIGS. 2 through 4 and FIG. 10, base 15 is rotatable relative to sleeve 25 of adjustable portion 20 around longitudinal axis 16 of base 15. By rotating base 15 relative to sleeve 25, device 10 is changed from a powered position (FIG. 2) to an unpowered position (FIG. 3). The relative rotational movement from powered to unpowered position provides contact electrical between power source 18 and transformer 19 in sleeve 25. FIGS. 4 and 10 show pin 24 and pin supports 26 and support channel in base 15 (shown) and sleeve 25, respectively that permits relative rotational movement. Base 15 also has a trigger 55 that is depressed to enable light source 70 to be activated.

During operation as shown in flowchart of FIG. 11, a user is able to power device 10 by rotating base 15 relative to sleeve 25, to provide electrical contact between chargeable battery 18 and transformer 19. A voltage develops across transformer 19 which builds an electrical charge in capacitor 23. When user places insertion tip 40 into nasal cavity and makes contact between skin at rim of nostrils and contacts 75, 77, a circuit is completed in board 27. Current is applied to primary winding of transformer. By completing circuit, trigger 55 is operable to administer phototherapy. If transformer 19 is at or near a set point of saturation, open switch to partially charge capacitor. Once capacitor voltage has reached set point, light source 70 is activated. Depression of trigger 55 discharges capacitor 23 and a circuit in board 27 delivers a high-voltage pulse to light source 70 that initiates a current flow in insertion tip 40. Device 10 is fully self-contained within housing 12 and a re-chargeable battery powers the control circuitry. Control circuitry contains either a logic circuit or suitable software to charge electrical system and to deliver a desired amount of illumination to nasal cavity. Light source 70 is controlled by circuitry to deliver approximately 12 to 24 Joules/cm² to nasal cavity of user. This dosage provides the desired efficacy without damaging or causing discomfort to the patient.

The present device 10 stimulates the human body's own respiratory system to reduce symptoms of allergic rhinitis. The typical human allergic response in the respiratory tract is characterized by two phases of the immune system. In the initial phase, after an allergen challenge is presented to the body (e.g. via the inhalation of dust, pollen, dust, or other allergens), resident mast cells in the nose and bronchi

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degranulate to release histamine as well as other vasoactive mediators (such as prostaglandins, leukotriens, etc.). These mediators typically cause localized itching and swelling of tissue, as well as an increase in the mucous production.

In a second phase of the allergic response, a myriad of inflammatory cells (such as activated T cell, eosinophils and basophils) are recruited to the inflammatory site. These inflammatory cells further inflame the local tissues, and typically perpetuate the inflammatory response for as long as the allergen is present. Allergy sufferers are familiar with these symptoms (itching and swelling of tissues, increased mucus production, etc.).

Studies have shown that those phases of the allergic response can be beneficially inhibited (to relieve the allergy sufferer) by the application of phototherapy, and that phototherapy can have profound immunosuppressive effects in such applications. In one such study, phototherapy significantly reduced the number of eosinophils and T cells by inducing apoptosis through a light-mediated alteration in Ca⁺ metabolism within these cells. Furthermore, phototherapy inhibited the release of histamines from basophils and mast cells. In short, these studies indicate that application of phototherapy can improve clinical symptoms such as sneezing, rhinorrhea (runny nose), nasal itching, and nasal congestion.

Thus, the present device 10 can be used to provide the desired phototherapy in the treatment of allergic rhinitis.

It should be understood that the foregoing description is only illustrative of the present disclosure. Various alternatives and modifications can be devices by those skilled in the art without departing from the disclosure. Accordingly, the present disclosure is intended to embrace all such alternatives, modification and variances that fall within the scope of the present disclosure.

I claim:

1. A device for delivering light to a nasal cavity comprising:
 - a base at a proximal end of the device, the base having a first end that is the proximal end and a second end opposite the first end;
 - a sleeve operably connected to the base at the second end;
 - an endpiece connected to the sleeve at a joint, wherein the endpiece has a curved end that moves in the sleeve during pivoting movement about the joint to change an angle between the sleeve and the endpiece, and wherein the angle is maintained by friction between an outer surface of the endpiece and an inner surface of the sleeve;
 - a tapered tip for insertion into the nasal cavity that is disposed at a distal end of the device and is operably connected to the endpiece;
 - a light source disposed inside the tapered tip; and
 - a power source to supply power to the device.

2. The device according to claim 1, wherein the angle is from 0° to 40°.

3. The device according to claim 2, wherein the base has a third longitudinal axis and the sleeve has a fourth longitudinal axis that is coincident with the third longitudinal axis, and wherein rotational movement between the base and the sleeve provides power to the device by completing a circuit.

4. The device according to claim 1, wherein the tapered tip has an air cavity providing insulation between the light source and an inner surface of the tapered tip.

5. The device according to claim 1, wherein the tapered tip has a first longitudinal axis and the light source has a second longitudinal axis, and wherein the first longitudinal axis and the second longitudinal axis are coincident to permit circumferential illumination of the tapered tip and the nasal cavity.

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6. The device according to claim 1, wherein the tapered tip is transparent.

7. The device according to claim 1, further comprising: a safety feature that restricts delivery of light from the light source to the nasal cavity.

8. The device according to claim 7, wherein the safety feature comprises a pressure sensor that detects pressure between the safety feature and an outer rim of a nostril of a user when the tapered tip is inserted into the nasal cavity, and wherein the safety feature enables illumination of the light source when pressure is detected and prevents illumination of the light source when pressure is not detected.

9. The device according to claim 8, wherein the safety feature is disposed on the endpiece, and wherein the safety feature comprises two arch shaped surfaces.

10. The device according to claim 9, wherein the two arch shaped surfaces complete a circuit when pressure from the nostril depresses the surfaces and completes the circuit.

11. The device according to claim 7, wherein the safety feature comprises an impedance sensor that detects contact between safety feature and an outer rim of a nostril of a user when the tapered tip is inserted into the nasal cavity to enable illumination of the light source and prevents illumination of the light source when contact is not detected.

12. The device according to claim 7, wherein the base further comprises a trigger that permits illumination of the light source when the safety feature is contacted by a nostril of a user.

13. The device according to claim 1, wherein the light source provides light in a wavelength of from 600-650 nm at a power of from 12 to 24 Joules/cm².

14. The device according to claim 1, wherein the power source is a chargeable battery.

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15. The device according to claim 1, wherein the light source is selected from the group consisting of: a flashlamp, a light emitting diode (LED), a fiber optic cable, and a laser beam.

16. The device according to claim 1, wherein the angle is about 0 to 30 degrees.

17. The device according to claim 1, wherein the base and the sleeve are in coaxial alignment, and wherein the base and the sleeve have rotational movement therebetween, wherein the rotational movement completes a circuit to supply power to the light source from the power source in a first position, and disrupts the circuit in a second position.

18. The device according to claim 1, wherein the angle is from 25° to 30°.

19. The device according to claim 1, wherein the angle is from 10° to 30°.

20. A method for treating rhinitis comprising:
 generating light in a wavelength of approximately 600 nm-650 nm in a tapered tip of a device that has a base at a proximal end of the device, wherein the base has a first end that is the proximal end and a second end opposite the first end, wherein the device has a sleeve operably connected to the base at the second end, wherein the device has an endpiece connected to the sleeve at a joint, wherein the endpiece has a curved end that moves in the sleeve during pivoting movement about the joint to change an angle between the sleeve and the endpiece; adjusting the angle between 0° and 40°, wherein the angle is maintained by friction between an outer surface of the endpiece and an inner surface of the sleeve;
 providing light to a nasal cavity of a user by inserting at least a portion of the tapered tip into the nasal cavity; and delivering a dosage of approximately 12 to 24 Joules/cm² of light energy to the nasal cavity.

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